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| 10/529,108 | 09/12/2005 | James C. Peacock III | 53233-00004 US | 1761 |

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| EXAMINER |
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HORNBERGER, JENNIFER LEA

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| ART UNIT | PAPER NUMBER |
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3734

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| NOTIFICATION DATE | DELIVERY MODE |
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10/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/529,108 | Applicant(s) PEACOCK ET AL. | |
| | Examiner JENNIFER L. HORNBERGER | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83,88-96,98 and 105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83,88-96,98 and 105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/17/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 83, 89, 90, 91, 92 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et al. (US 2003/0023301).

Regarding claim 83, Cox et al. disclose a stent assembly comprising: an expandable stent (21; Fig. 7) and a delivery system (Fig. 2); said expandable stent having a length and having a plurality of longitudinally spaced, networked segments extending along a first end portion, a second end portion. and a central portion disposed between said first and second end portions and including a mid-point along the length, with said first end portion (23B), said second end portion (23A) and said central portion (23C) defining a longitudinal axis along the length of said stent; said first end portion comprising at least a first one of said longitudinally spaced, networked segments at a first terminal end of the stent having a first lattice structure when the stent is expanded to a radially expanded condition; said second end portion comprising a second one of said longitudinally spaced, networked segments having a second lattice structure when the stent is expanded to the radially expanded condition; and wherein said first and second lattice structures are different (Fig. 7); said central portion comprising at least a third one of said longitudinally spaced, networked segments having a third lattice structure when

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the stent is expanded to the radially expanded condition; said third lattice structure is substantially similar to said second lattice structure; said first lattice structure comprising a first circumferentially undulating pattern with a plurality of first strut segments wherein a circumferential array of M first end crowns is formed between adjacent first strut segments with said first undulating pattern having a first amplitude between adjacent first end crowns and a first inter-crown distance between facing sides of adjacent first end crowns; said second lattice structure comprising a second circumferentially undulating pattern with a plurality of second strut segments wherein a circumferential array of N second end crowns is formed between adjacent second strut segments with said second undulating pattern having a second amplitude between adjacent second end crowns and a second inter-crown distance between facing sides of adjacent second end crowns; N is greater than M; said first amplitude is greater than the second amplitude; said first inter-crown distance is greater than the second inter-crown distance; said delivery system having a distal end portion and a proximal end portion; wherein said expandable stent is located along the distal end portion of the delivery system in a radially collapsed condition and is expandable by the delivery system from the radially collapsed condition to the radially expanded condition; and wherein the radially expanded condition comprises a substantially tubular structure along the length (Fig. 7).

Regarding claim 89, Cox et al. disclose said first amplitude is about twice said second amplitude (Fig. 7).

Regarding claim 90, Cox et al. disclose said first lattice structure comprises a circumferentially undulating pattern with a plurality of strut segments wherein said circumferential array of M first end crowns is formed between adjacent converging strut segments; and at least one of said first end crowns comprises a curvilinear bulb-shaped

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member extending longitudinally and circumferentially from respective ends of two converging strut segments (Fig. 7).

Regarding claim 91, Cox et al. disclose each of said first end crowns comprises a curvilinear bulb-shaped member extending longitudinally and circumferentially from respective ends of two adjacent converging strut segments (Fig. 7).

Regarding claim 92, Cox et al. disclose in radially expanded condition: said first inter-crown distance is about twice said second inter-crown distance (Fig. 7).

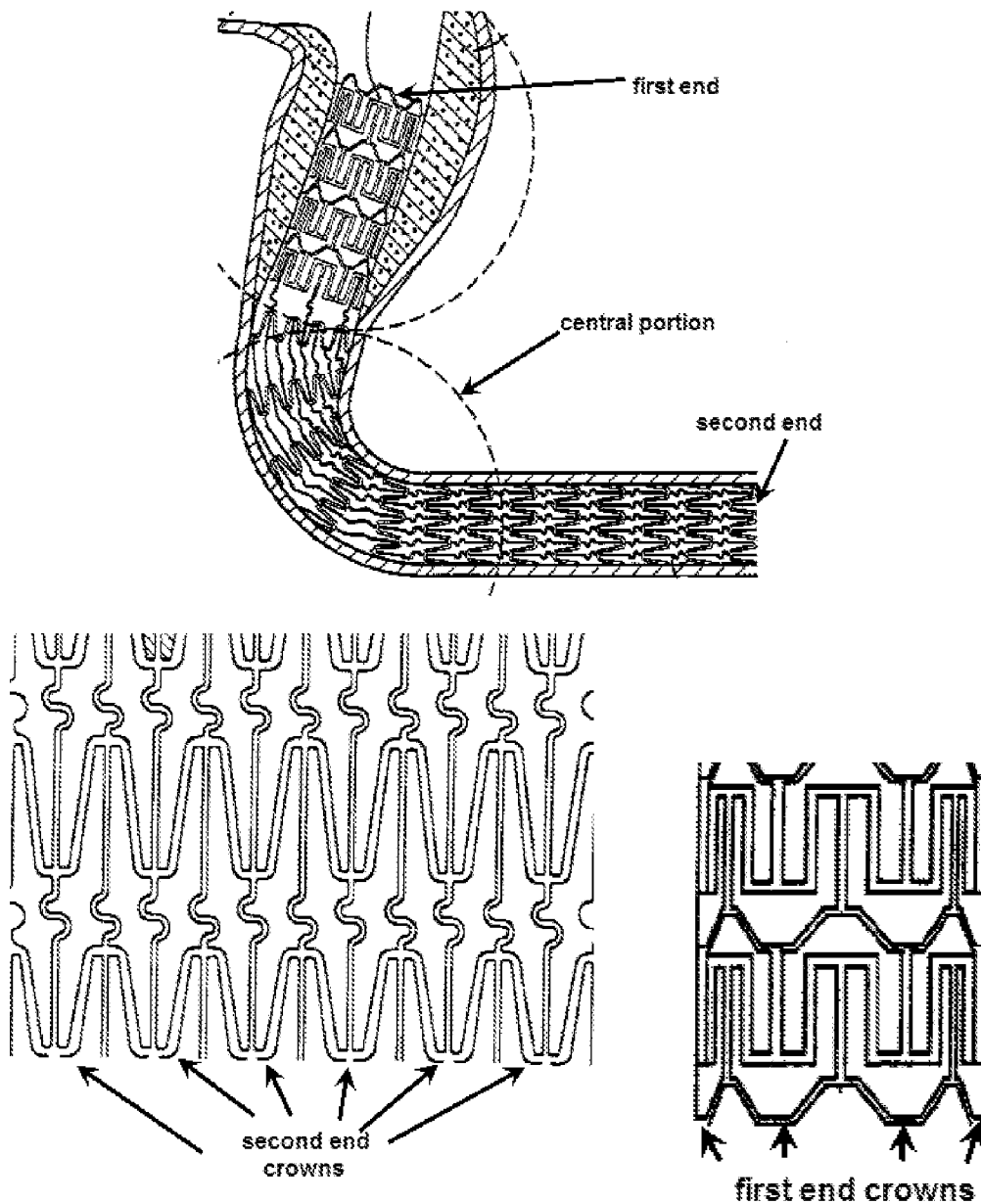
3. Claims 83, 89, 90, 91, 92 are rejected under 35 U.S.C. 102(e) as being anticipated by Penn et al. (US 6,375,677).

Regarding claim 83, Penn et al. disclose a stent assembly comprising: an expandable stent (Fig. 11) and a delivery system (col. 13, ln.31-33); said expandable stent having a length and having a plurality of longitudinally spaced, networked segments extending along a first end portion, a second end portion, and a central portion disposed between said first and second end portions and including a mid-point along the length, with said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of said stent (see figure below); said first end portion comprising at least a first one of said longitudinally spaced, networked segments at a first terminal end of the stent having a first lattice structure when the stent is expanded to a radially expanded condition; said second end portion comprising a second one of said longitudinally spaced, networked segments having a second lattice structure when the stent is expanded to the radially expanded condition; and wherein said first and second lattice structures are different (see figure below); said central portion comprising at least a third one of said longitudinally spaced, networked segments having a third lattice structure when the stent is expanded to the radially expanded condition; said third lattice structure is substantially similar to said second lattice structure (see figure below); said first lattice structure

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(Figure 1) comprising a first circumferentially undulating pattern with a plurality of first strut segments wherein a circumferential array of M first end crowns (see figure below) is formed between adjacent first strut segments with said first undulating pattern having a first amplitude between adjacent first end crowns and a first inter-crown distance between facing sides of adjacent first end crowns; said second lattice structure (Figure 8) comprising a second circumferentially undulating pattern with a plurality of second strut segments wherein a circumferential array of N second end crowns (see figure below) is formed between adjacent second strut segments with said second undulating pattern having a second amplitude between adjacent second end crowns and a second inter-crown distance between facing sides of adjacent second end crowns; N is greater than M; said first amplitude is greater than the second amplitude; said first inter-crown distance is greater than the second inter-crown distance; said delivery system having a distal end portion and a proximal end portion; wherein said expandable stent is located along the distal end portion of the delivery system in a radially collapsed condition and is expandable by the delivery system from the radially collapsed condition to the radially expanded condition; and wherein the radially expanded condition comprises a substantially tubular structure along the length.

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Regarding claim 88, Penn et al. disclose N is about twice M (see figures above).

Regarding claim 89, Penn et al. disclose said first amplitude is about twice said second amplitude (see figures above).

Regarding claim 92, Penn et al. disclose in radially expanded condition: said first inter-crown distance is about twice said second inter-crown distance (see figures above).

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4. Claim 105 is rejected under 35 U.S.C. 102(e) as being anticipated by McGuinness (US 6,485,508). McGuinness discloses a stent (3) having a length between first and second ends and having a first end portion that terminates in the first end, a second end portion that terminates in the second end, and a central portion and that includes a midpoint between two opposite ends, and also disposed between said first and second end portions with said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of said stent; said being stent made of a non-superelastic, non-shape memory metal alloy (col. 5, ln. 1-3 and 41-59); said stent having a radially collapsed condition with a collapsed diameter (col. 6, ln. 54), for delivery to a location within a lumen, said collapsed diameter being plastically deformed from an initial condition having an initial diameter (col. 5, ln. 44-45); wherein at said location said stent is expanded by the application of force (col. 4, ln.21-24) from said collapsed diameter to a radially expanded diameter (col. 5, ln. 43) that is greater than the collapsed diameter; and wherein said initial diameter has a value that is closer to said expanded diameter than to said collapsed diameter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (US 2003/0023301) in view of Santos et al. (US 7,169,178).

Cox et al. disclose said stent assembly is adapted to be delivered by the delivery system to a location in a lumen, wherein said first end portion is adapted to deliver a lower density therapeutic dose of the bioactive agent to tissue at said location of said lumen than said second

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end portion and said central portion. Cox et al. fails to disclose a bioactive agent coupled to the stent assembly. Santos et al. disclose a bioactive coating coupled to the stent, a first elution profile along that portion of the longitudinal axis defined by the first end portion; a second elution profile along that portion of the longitudinal axis defined by the second end portion; a third elution profile along that portion of the longitudinal axis defined by the central portion; and wherein the first elution profile is greater than the third elution profile thereby the stent exhibits a gradient of elution profile with respect to the bioactive agent between the two opposite ends of the stent (Fig. 5; col. 3, ln. 44-67). Santos et al. disclose that varying drug concentration or the release rate of the drug from the coating provides uniform drug delivery along the length of the stent (col. 3, ln. 63-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a stent with a bioactive agent so the stent exhibits a gradient elution profile along the length of the stent as taught by Santos et al. in order to provide uniform drug delivery to the target site.

7. Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Penn et al. (US 6,375,677) in view of Santos et al. (US 7,169,178).

Penn et al. disclose said stent assembly is adapted to be delivered by the delivery system to a location in a lumen, wherein said first end portion is adapted to deliver a lower density therapeutic dose of the bioactive agent to tissue at said location of said lumen than said second end portion and said central portion. Cox et al. fails to disclose a bioactive agent coupled to the stent assembly. Santos et al. disclose a bioactive coating coupled to the stent, a first elution profile along that portion of the longitudinal axis defined by the first end portion; a second elution profile along that portion of the longitudinal axis defined by the second end portion; a third elution profile along that portion of the longitudinal axis defined by the central portion; and wherein the first elution profile is greater than the third elution profile thereby the

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stent exhibits a gradient of elution profile with respect to the bioactive agent between the two opposite ends of the stent (Fig. 5; col. 3, ln. 44-67). Santos et al. disclose that varying drug concentration or the release rate of the drug from the coating provides uniform drug delivery along the length of the stent (col. 3, ln. 63-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a stent with a bioactive agent so the stent exhibits a gradient elution profile along the length of the stent as taught by Santos et al. in order to provide uniform drug delivery to the target site.

8. Claims 94, 95, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (US 2003/0023301) in view of Brightbill (US 7,083,822) and Marin et al. (US 5,697,948).

Regarding claim 94, Cox et al. disclose a stent assembly for implanting a stent at a location within a lumen, comprising: a first delivery system (Fig. 2) having a proximal and distal end that is adapted to be positioned at a location within a lumen; a stent (21; Fig. 7) with a length extending between first and second opposite ends, and having a plurality of longitudinally spaced, networked segments extending between the first and second ends including along a first end portion that terminates in the first end, a second end portion that terminates in the second end opposite the first end, and a central portion disposed between said first and second end portions and including a mid-point of the length; said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of each of said stent; each of said first end portions having a first lattice structure (23B) that is different than a second lattice structure (23A) along the corresponding second end portion and that is also different than a third lattice structure (23C) along the corresponding central portion. Cox et al. fail to disclose implanting at least two stents in overlapping configuration at a location within the lumen and a second delivery system. Brightbill discloses an assembly for implanting at least

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two stents in overlapping configuration at a location within a lumen, comprising: first and second delivery systems having a proximal and distal end that is adapted to be positioned within a lumen (col. 1, ln. 19-29, col. 5, ln. 64-67); said first stent being mounted on the distal end of said first delivery system with said first end portion located proximally of said second end portion; said second stent being mounted on the distal end of said second delivery system with said first end portion located distally of said second end portion; each of said first and second stents being mounted on the respective delivery system in a radially collapsed condition for delivery to said location; wherein at said location each of the said first and second stents is adjustable by the respectively mounted delivery system from the respective radially collapsed condition to a radially expanded condition; with the respective stents in opposite respective longitudinal orientations and in an overlapping configuration with the respective first end portions overlapped at an overlap region and the respective second end portions extending away in opposite relative longitudinal orientation from the overlap region, and such that said overlapping configuration comprises a substantially tubular structure along a length extending between the second opposite ends of the respectively overlapped stents. Brightbill discloses overlapping the stents to treat an area greater in length than an individual stent (col. 2, ln. 1-9). It would have been obvious to one of ordinary skill in the art to provide a second stent substantially similar to the stent disclosed by Cox et al. and a second delivery system in order to provide support to a treatment site longer than an individual stent as suggested by Brightbill. Cox et al. in view of Brightbill fail to disclose overlapping the first ends of the first and second stents. However, it would have been obvious to one of ordinary skill to determine the optimal orientation for the overlapping stents given that there is a limited number of ways orient the stents in an overlapping configuration. Cox et al. in view of Brightbill fail to disclose the first and second delivery systems are configured to deliver and implant the first and second stents in

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series over a common guidewire. However, Marin et al. disclose first and second delivery systems configured to deliver and implant first and second stents in series over a common guidewire (col. 7, ln. 51-60; col. 6, ln. 39-44). It would have been obvious to one of ordinary skill in the art to configure the first and second delivery systems to deliver the stents over a common guidewire in order to allow simple delivery of the delivery systems to the lumen.

Regarding claim 95, Cox et al. disclose said first lattice structure (23B) comprises a first circumferentially undulating pattern with a plurality of first strut segments wherein said circumferential array of M first end crowns is formed between adjacent first strut segments with said first undulating pattern having a first amplitude; said second lattice structure (23A) comprises a second circumferentially undulating pattern with a plurality of second strut segments wherein said circumferential array of N second end crowns is formed between adjacent second strut segments with said second undulating pattern having a second amplitude; and wherein said first and second amplitudes are different (Fig. 7).

Regarding claim 98, Cox et al. fail to disclose a bioactive agent in association with said first and said second stent. Brightbill discloses that overlapping drug coatings may result in over dose of the therapeutic agent. Brightbill discloses evenly coating all of one stent (320) and coating the second stent (310) with the same amount of coating except for in the section which is to overlap with the first stent (col. 4, ln. 52 – col. 5, ln. 8). Since the elution over the stents when overlapped remains constant over the entire length of the stent, the elution profile at the overlapping portion is equal to the elution profile of the second end and central portions and is therefore substantially less than double the elution profile along the respective second end and central portions of the first and second stents. It would have been obvious to coat the stents of Cox et al. with a bioactive agent in the manner as disclosed by Brightbill to prevent too much of the therapeutic agent from being delivered at the overlapping region.

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9. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (US 2003/0023301) in view of Brightbill (US 7,083,822) and Marin et al. (US 5,697,948) as applied to claim 94 above, and further in view of Santos et al. (US 7,169,178). Cox et al. fail to disclose a bioactive agent in association with said first and said second stent. Santos et al. disclose a bioactive agent in association with a stent, said first end portion is adapted to elute said bioactive agent according to a first elution profile; said second end portion is adapted to elute said bioactive agent according to a second elution profile; said central portion is adapted to elute said bioactive agent according to a third elution profile; and wherein said first elution profile is substantially less than either the second or third elution profile (Fig. 5; col. 3, ln. 44-67). Santos et al. disclose that varying drug concentration or the release rate of the drug from the coating provides uniform drug delivery along the length of the stent (col. 3, ln. 63-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a both stents of Cox et al. as modified by Brightbill with a bioactive agent so the stent exhibits a gradient elution profile along the length of the stent as taught by Santos et al. in order to provide uniform drug delivery to the target site.

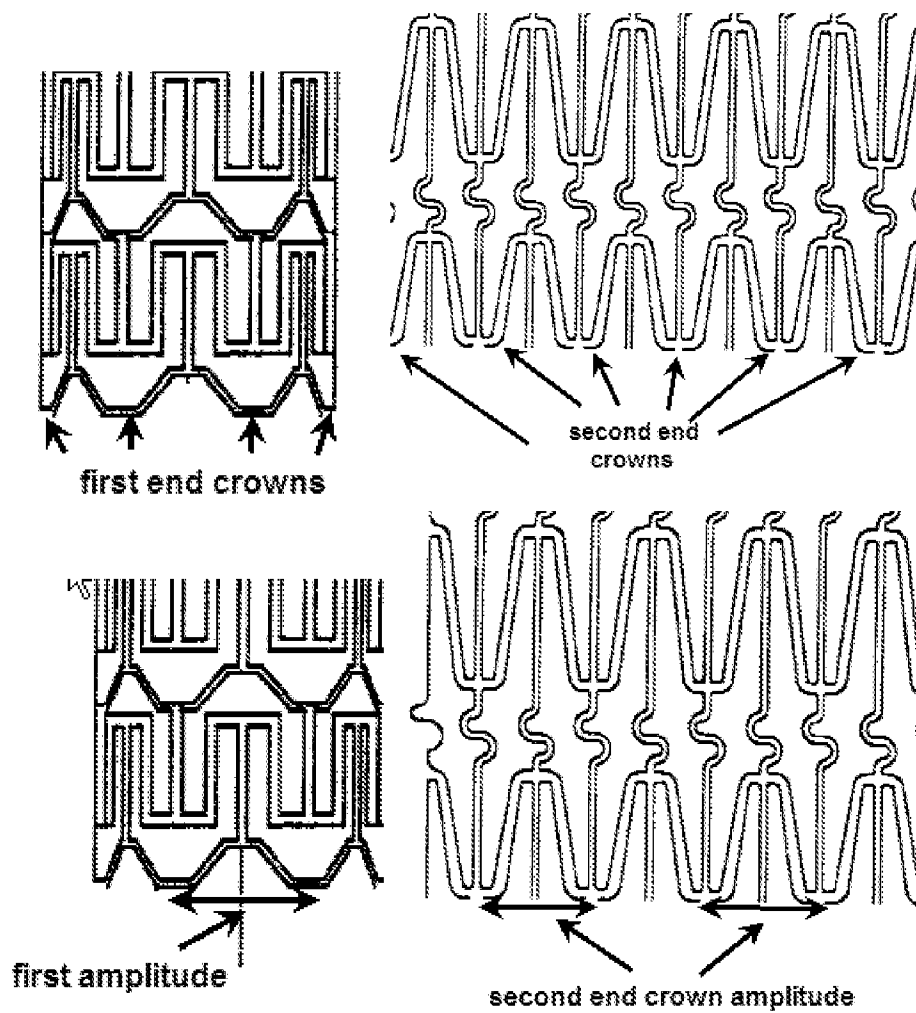
Response to Arguments

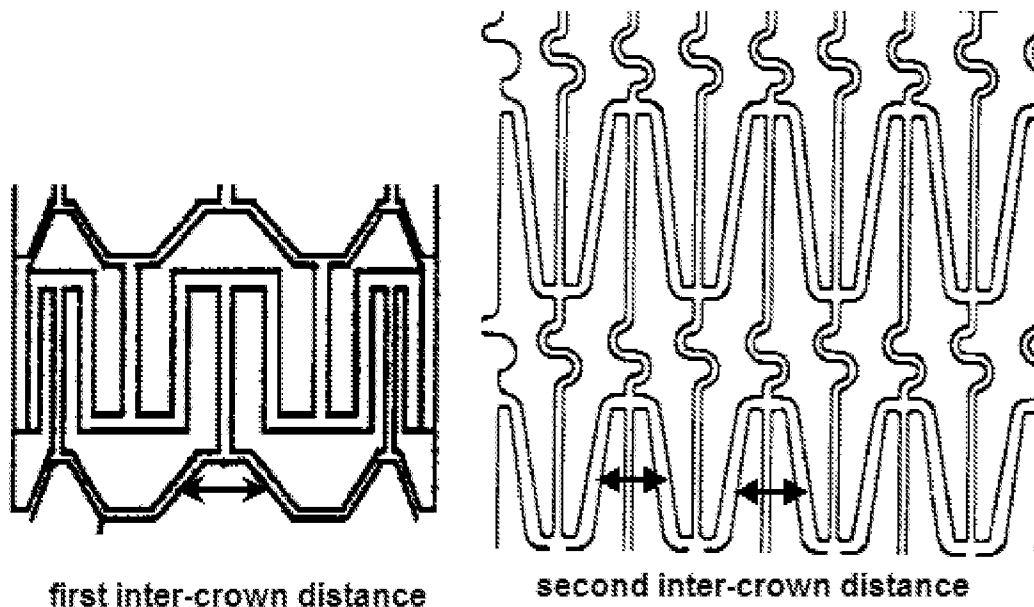
10. Applicant argues that Cox et al. fails to anticipate independent claim 83 because second end portion (23A) and central portion (23C) do not have substantially similar lattice structure and that central portion (23C) has lattice structure that is similar to that of the first portion (23B). The examiner respectfully disagrees. Second end portion (23A) and the central portion (23C) are **substantially** similar because the central portion is a larger version of the second portion (23A), whereas the first portion (23B) is different because it lacks the interconnecting member (13) which is present in both the second portion (23A) and the central portion (23C).

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11. Applicant argues that Penn et al. fails to anticipate independent claim 83 because the second end portion and the central portion are not substantially similar. The examiner respectfully disagrees. The lattice structure of the second end portion (see figure above) and the central portion (see figure above) are substantially similar. Penn et al. disclose that figure 11 illustrates substantially complementary extension and compression of the longitudinal members in the central portion or region X when placed in the right coronary artery (col. 12, ln. 46-49). Examiner submits that in the absence of the complementary extension and compression of the longitudinal members, for example before deployment or when deployed in a straight lumen, the central portion and second portion have substantially similar lattice structure. Further, applicant argues the amplitude of the first portion of the first end crown3s in not greater than the amplitude of the second end crowns. Examiner respectfully disagrees. The first end crowns and second end crowns are labeled in the figures again provided below. Claim 83 requires a "first amplitude between adjacent first end crowns" and "second amplitude between second adjacent end crowns". To further clarify examiner's position, the first and second amplitudes as interpreted measured between first adjacent end crowns and second adjacent end crowns by the examiner are labeled in the figures below. As the figures provided below enlarged to better show the features of the stent structure, Figure 11 provides a better idea of the size of the first and second amplitudes (as identified by the examiner) relative to each other. The first and second inter-crown distances, formed between facing sides of adjacent first end crowns and facing sides of adjacent second crowns, are labeled in the figures below.

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12. Applicant pointed out that the reference of Marin et al. relied upon in the rejection of claims 94, 95, and 98 was omitted from the rejection line in the previous office action. This omission has been corrected, and the finality of the last office action is withdrawn.

13. Applicant's arguments with respect to claim 105 are moot in view of a new grounds of rejection.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
10/01/2009

***/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734***